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BARNES & THORNBURG LLP			KUMAR, VINOOD	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent-ch@btlaw.com

Office Action Summary	Application No. 10/556,669	Applicant(s) BRESSAN, RAY A.
	Examiner VINOD KUMAR	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 25 March 2011.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-24 is/are pending in the application.
 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-19,22 and 23 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 04 November 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Status of Objections & Rejections

1. Applicant's response filed 3/25/2011 is entered. Claims 1-23 and newly added claim 24 are pending. Claims 20-21 are previously withdrawn. Newly added claim 24 falls within the scope of the elected invention. Accordingly, claims 1-19 and 22-24 are examined on merits in the present Office action.
2. Objection to the specification is withdrawn in light of amendments to the specification filed in the paper of 3/25/2011.
3. Objections to claims 1, 2, 5, 7-9, 11, 16, 17 and 19 made in the Office action mailed 12/27/2010 are withdrawn in light of amendments to the claims filed in the paper of 3/25/2011.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Rejection of claims 1-6, 8, 12, 16-17, 19 and 22-23 under 35 U.S.C. 112, second paragraph is withdrawn in light of amendments to the claims filed in the paper of 3/25/2011.
6. Rejection of claims 1-4, 6-7, 11 and 22-23 under 35 U.S.C. 112, first paragraph (scope of enablement) is withdrawn in light of amendments to the claims filed in the paper of 3/25/2011.

Claim Objections

7. Claims 12, 18 remain, and claim 9 is objected to because of the following informalities:

Claim 12 remains objected for reciting "SEQ ID NO: 2". It may be noted that SEQ ID NO: 1 is a polypeptide, whereas SEQ ID NO: 2 is a polynucleotide sequence.

Claims 18 remains objected for reciting "an HOS10 polypeptide (SEQ ID NO: 1)". It is suggested to change "an HOS10 polypeptide (SEQ ID NO: 1)" to --a HOS10 polypeptide as set forth in SEQ ID NO: 1--.

In claim 19, it is suggested to insert “cell” after “plant” in line 3.

Claim 9 is objected under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Parent claim 8 is limited to HOS10 protein of SEQ ID NO: 1, whereas claim 9 encompasses a HOS10 protein comprising SEQ ID NO: 1. Dependent claim 9 fails to limit the scope of parent claim. This objection is necessitated due to the amendment to claim 8 filed in the paper of 3/25/2011.

Applicant is advised that should claim 3 be found allowable, newly added claim 24 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, newly added claim 24 recites “DNA is stably integrated”. Since DNA is only stably integrated into plant’s genome, and thus newly added claim 24 falls within the scope of claim 3.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. Claims 7 and 18 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation “different from HOS10, from signaling pathways conserved among dicots and monocots” which is confusing since it is unclear which different signaling pathways that are different from HOS10

but conserved among dicots and monocots" are being referred to. It is unclear to evaluate the scope of the recitation. It is unclear what is intended.

Claim 18 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite in reciting a recitation within parenthesis, since it is unclear whether the recitation within the parenthesis is a part of the claim limitation.

9. Claims 1, 3-4, 6-7, 11, 22 and 23 remain, and newly added claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record stated in the Office action mailed 12/27/2010.

Applicant traverses the rejection in the paper filed 3/25/2011.

Applicant primarily argues that the specification provides support for the sequences that fall within the scope of 90% identity to SEQ ID NO: 1 and thus meet written description requirements. Applicant further argues that one skilled in the art would know how to find homologs of SEQ ID NO: 1 having the same function as instant SEQ ID NO: 1 (response page 11).

Applicant's arguments are carefully considered but are deemed to be unpersuasive.

The essential feature of claims 1, 11 and 22 is a DNA molecule that encodes a polypeptide having 90% identity to SEQ ID NO: 1.

It is maintained that the claims encompass a polypeptide having unspecified changes in the amino acid sequence of SEQ ID NO: 1.

Contrary to Applicant's arguments, the instant specification only describes SEQ ID NO: 2 and its encoded protein of SEQ ID NO: 1 which has cold tolerant property upon over-expression in a plant. See in particular, pages 11-12, examples 1-2; table.

It is maintained that the specification does not describe structure for a representative species of Applicant's broadly claimed genus and thus their function is unknown.

It is further maintained that there is no description of the structure required for the recited function, and no description of the necessary and sufficient elements of functional activity (e.g. increased or improved stress tolerance) of SEQ ID NO: 1.

It is further maintained that one of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NOs: 1 and 2 are insufficient to describe the claimed genus.

Applicant is reminded that the Federal Circuit has clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Thus, under *Lilly* and its progeny, the Specification does not show possession of a sufficient number of sequences falling within their potentially large genus to establish possession of their claimed genus. See *Cf Enzo*, 323 F.3d at 964 ("if the functional characteristic of... binding to [CD48] were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed," the written description requirement may be met). Without a correlation between structure and function, the claim does little more than define the claimed invention by function. That is not sufficient to satisfy the written description requirement. *See Eli Lilly*, 119 F.3d at 1568, ("definition by function ... does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is"); *see also Kubit*, 83 USPQ2d at 1416-17.

Applicant fails to describe a representative number of recombinant DNA sequences encoding protein(s) that fall within the scope of the claimed genus of recombinant DNA sequences encoding protein(s) having at least 90% identity to instant SEQ ID NO: 1. Applicant only describe a single species of SEQ ID NO: 1. Furthermore, Applicant fails to describe structural features common to members of the claimed genus of recombinant DNA sequence encoding polypeptide(s) having 90% identity to SEQ ID NO: 1. Hence, Applicant fails to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the polypeptide of SEQ ID NO: 1, it remains unclear what features identify the protein of SEQ ID NO: 1. Since the genus of protein(s) having 90% identity to SEQ ID NO: 1 has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Also see *in re Curtis* (69 USPQ2d 1274 (Fed. Cir. 2004), where the court held that there was sufficient evidence to indicate that one of ordinary skill in the art could not predict the operability of other species other than the single one disclosed in the specification. The court held that a disclosure naming a single species can support a claim to a genus that includes that species if a person of ordinary skill in the

art, reading the initial disclosure, would “instantly recall” additional species of the genus already “stored” in the minds, but if other members of the genus would not “naturally occur” to a person of ordinary skill upon reading the disclosure, then unpredictability in performance of species other than specifically enumerated defeats claims to the genus.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

In view of above, the requirement for written description has not been met.

Claim Rejections - 35 USC § 102

10. Claims 1-6, 8-19 and 22-23 remain, and newly added claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Alexandrov et al. (EP 1033405 A2, Published June 9, 2000) for the reasons of record stated in the Office action mailed 12/27/2010.

Applicant traverses the rejection in the paper filed 3/25/2011.

Applicant argues that Zhu et al. cannot be considered as an evidence for cold tolerant property of instant SEQ ID NO: 1 because Zhu et al. was retracted. Applicant also argues that inherency cannot be based on the knowledge of the inventor and facts must be present in the prior art reference. Applicant further argues that inherency cannot be established by probabilities or possibilities (response, pages 7-8).

Applicant is right that Zhu et al. was retracted. While Zhu et al. reference may not be used as an evidence for the inherently present cold tolerant property of Alexandrov et al. protein, however it is important to note that the present anticipation analysis is not based on Zhu et al. disclosure. It may also

be noted that Zhu et al. do not provide any evidence against the inherent cold tolerance property of Alexandrov et al. protein of SEQ ID NO: 67645. The anticipation analysis is entirely based on Alexandrov et al. disclosure. Furthermore, Alexandrov et al. do disclose stress (e.g. osmotic) tolerant property of SEQ ID NO: 67645 and not all claims require cold tolerant property of instant SEQ ID NO: 1.

It is maintained that while Alexandrov et al. do not explicitly disclose cold tolerance property of their transgenic plants or seeds derived thereof, such a property would be inherent to the transgenic plant comprising over-expressing Alexandrov et al. polypeptide of SEQ ID NO: 67645 (identical in sequence to instant SEQ ID NO: 1, emphasis added) in Alexandrov et al. transgenic plant or seeds derived thereof.

It is also important to note that Alexandrov et al. transgenic seeds would be inherently produced during sexual crosses as disclosed in Alexandrov et al., which are structurally identical to instantly claimed transgenic seed because both comprise expression of the same transgenic protein.

Applicant's attention is also drawn to *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1348 (Fed. Cir. 2004), on which the district court relied, which states: "Apotex is of course correct that anticipation requires that all limitations of the claimed invention are described in a single reference, rather than a single example in the reference." This language, when read in context, stands for the unremarkable proposition that courts are not constrained to proceed example-by-example when reviewing an allegedly anticipating prior art reference. Rather, the court must, while looking at the reference as a whole, conclude whether or not that reference discloses all elements of the claimed invention. This implies that while it is important that the reference discloses all the claimed elements in a single reference but it is not necessary that all the claimed elements are disclosed in a single example. In the instant case, Alexandrov et al. disclose all the claimed structural elements in the same reference. Also see the Xerox, 458 F.3d at 1322 (quoting *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272,

1282 (Fed. Cir. 2000), wherein court has ruled that in order to demonstrate anticipation, the four corners of a single, prior art document should describe every element of the claimed invention.

Additionally, it may be noted that Alexandrov et al. disclose all the structural elements of the claims under rejection. It does not matter in which order said elements are disclosed. The reference is presumed to be enabled. See *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See also MPEP § 716.07.

See *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1346-48, 64 USPQ2d 1202, 1204-05 (Fed. Cir. 2002) where a claim at issue was directed to a method of preparing a food rich in glucosinolates wherein cruciferous sprouts are harvested prior to the 2-leaf stage. The court held that the preamble phrase “rich in glucosinolates” helps define the claimed invention, as evidenced by the specification and prosecution history, and thus is a limitation of the claim (although the claim was anticipated by prior art that produced sprouts inherently “rich in glucosinolates”).

Also see *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC Scalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then prior art anticipates the claimed invention.

It may also be emphasized that something which is old does not become patentable upon the discovery of a new property. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. See also *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01.

It is thus maintained that Alexandrov et al. disclose a method of producing a transgenic plant cell comprising transformation of said plant cell with a plant transformation vector comprising an expression cassette which comprises a nucleic acid sequence (SEQ ID NO: 67644, identical to instant SEQ ID NO: 2) encoding a polypeptide (SEQ ID NO: 67645) which is identical in sequence to instant SEQ ID NO: 1. The reference further discloses that the vector which comprises a gene construct having an expression cassette which comprises said nucleic acid sequence is operably linked to a promoter (constitutive, tissue-specific or inducible) which is inherently capable of causing transcription in a plant cell (see pages 22-23, and 327-329), and wherein said promoter is either native or heterologous (non-native) to the nucleic acid sequence disclosed in the reference. The reference further discloses that said promoter is a stress-inducible promoter, such as ABA-inducible or ethylene responsive promoter. The reference also discloses that said promoter is a tissue specific promoter, such as a root-specific or leaf specific promoter. The reference also discloses that said promoter is a CAMV 35S promoter, and wherein said plant is a dicot or monocot plant species. The reference further discloses regenerating a transgenic plant from said transformed plant cell. The reference also discloses transgenic plants over-expressing the nucleic acid sequence encoding the polypeptide disclosed in the reference. The reference further discloses that said transgenic plant is rapeseed, or soybean (dicot and legume). The reference also discloses producing transgenic seeds from said transgenic plant. The reference further discloses that SEQ ID NO: 67645 is a HOS10 (high response to osmotic stress) transcription factor. The reference also discloses stably incorporating the expression cassette in transgenic plants and then introducing into other plants by sexual crossing using standard breeding techniques. See paragraph 2307 at page 329. It may be noted that propagating transgenic plants through sexual crossing would inherently comprise obtaining transgenic seeds. The reference further discloses that SEQ ID NO: 67644 encoding HOS10 (a MYB transcription factor) protein of SEQ ID NO: 67645 is induced under osmotic stress. See in particular, claims 1-34,

pages 327- 335, 341-343, and SEQ ID NOS: 67644 and 67645.

Accordingly, Alexandrov et al. anticipated the claimed invention.

Claim Rejections - 35 USC § 103

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alexandrov et al. (EP 1033405 A2, Published June 9, 2000) for the reasons of record stated in the Office action mailed 12/27/2010.

Applicant traverses the rejection in the paper filed 3/25/2011.

Applicant primarily argues that since Alexandrov et al. do not teach transgenic plant expressing SEQ ID NO: 67645, it would not have been obvious to arrive at the claim 7 (response, pages 8-9).

Applicant's arguments are carefully considered but are deemed to be unpersuasive.

Contrary to Applicant's arguments, Alexandrov et al. do teach a method of producing a transgenic plant cell comprising transformation of said plant cell with a plant transformation vector comprising an expression cassette which comprises a nucleic acid sequence (SEQ ID NO: 67644, identical to instant SEQ ID NO: 2) encoding a polypeptide (SEQ ID NO: 67645) which is identical in sequence to instant SEQ ID NO: 1. The reference further teaches that the vector which comprises a gene construct having an expression cassette which comprises said nucleic acid sequence is operably linked to a promoter (constitutive, tissue-specific or inducible) which is inherently capable of causing transcription in a plant cell (see pages 22-23, and 327-329), and wherein said promoter is either native or heterologous (non-native) to the nucleic acid sequence taught in the reference. The reference further teaches that said promoter is a stress-inducible promoter, such as ABA-inducible or ethylene responsive promoter. The reference also teaches that wherein said promoter is a tissue specific promoter, such as a root-specific or leaf specific promoter. The reference also teaches that said promoter is a CAMV 35S promoter, and wherein said plant is a dicot or monocot plant species. The reference further teaches regenerating a

transgenic plant from said transformed plant cell. The reference also teaches transgenic plants over-expressing the nucleic acid sequence encoding the polypeptide disclosed in the reference. The reference further teaches that said transgenic plant is rapeseed, or soybean (dicot and legume). The reference also teaches producing transgenic seeds from said transgenic plant. The reference further teaches that SEQ ID NO: 67645 is a HOS10 (high response to osmotic stress) transcription factor. The reference also teaches stably incorporating the expression cassette in transgenic plants and then introducing into other plants by sexual crossing using standard breeding techniques. See paragraph 2307 at page 329. It may be noted that propagating transgenic plants through sexual crossing would comprise obtaining transgenic seeds. More importantly, Alexandrov et al. do teach stress (e.g. osmotic) tolerant property of SEQ ID NO: 67645. See in particular, claims 1-34, pages 327- 335, 341-343, and SEQ ID NOs: 67644 and 67645.

It is therefore, maintained that it would have been obvious and within the scope of an ordinary skill in the art to have transformed stress tolerant transgenic plant overexpressing HOS10 polypeptide of SEQ ID NO: 67645 with an additional recombinant polynucleotide encoding a different and unrelated transcription factor of Alexandrov et al. (for example, a DOF-type zinc finger domain containing transcription factor, transcription factors involved in disease resistant cited in the reference) to arrive at the claimed invention with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to do so for the purpose of imparting stress tolerance to other environmental stress responsive factors other than cold, osmotic stress, drought or abscisic acid in the transgenic plant overexpressing Alexandrov et al. protein with a reasonable expectation of success.

See the recent Board decision *Ex parte Smith*, -- USPQ2d --, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR*, 82 USPQ2d at 1396). KSR forecloses the argument that a **specific** teaching, suggestion or motivation is required to support a finding of obviousness.

Thus, the claimed invention as a whole is *prima facie* obvious teachings of the prior art.

Conclusions

12. Claims 1-19 and 22-23 remain, and newly added claim 24 is rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Vinod Kumar/
Primary Examiner, Art Unit 1638